

**REMARKS**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

**Claim Amendments**

Claims 1-37 are canceled.

New claims 38-48 are added above. Support for the new claims may be found throughout the specification as filed and in originally filed claims 1-37. The following table correlates the newly presented claims with exemplary support in the specification as filed and in the originally filed claims.

<b>Newly presented claim</b>	<b>Support in Specification</b>
38	Original claim 27; page 4, [0011]; page 6, [0022]; page 14, [0059]; page 27, [0104]
39	Original claims 30 and 31; page 4, [0011]; page 7, [0024]; page 14, [0059]; page 27, [0104]
40	Original claim 20; page 4, [0011]; page 6, [0020]; page 27, [0104]
41	page 4, [0013]; page 6, [0020], [0022]; page 7, [0024]; page 15, [0062]; page 16, [0065]
42	page 15, [0062]; page 18, [0069];
43	Original claim 27 and page 4, [0013]; page 18, [0069]
44	Original claims 30 and 31 and page 4, [0013]; page 18, [0069]
45	Original claim 20 and page 4, [0013]; page 6, [0020]; page 15, [0062]; page 16, [0065] ; page 18, [0069]
46	page 15, [0062]; page 18, [0069]
47	page 4, [0012]
48	page 4, [0012]

In particular, support for the terms “HIF $\alpha$  stabilizer” and “HIF hydroxylase inhibitor” as recited in new claims 38-48 may be found throughout the specification as filed, for example,

at pages 4-5, [0014]; pages 15-16, [0063]; page 16, [0064]; page 35, [0133];  
and pages 35-36, [0134].

This Amendment adds and deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, *supra*, with appropriate defined status identifiers.

Applicants submit that no new matter is added by any of the above amendments and entry of these amendments is therefore respectfully requested. Applicants specifically reserve the right to file continuing applications directed to any canceled subject matter.

#### **Information Disclosure Statement**

Applicants submit on even date herewith a Supplemental Information Disclosure Statement and request consideration of the references identified therein by the Office.

#### **Previously Filed Amendments and Remarks**

Applicants hereby withdraw all previously filed amendments and remarks. Applicants request that the Office not rely on any previously filed amendments and remarks heretofore presented.

In an effort to expedite prosecution, Applicants will apply the previously stated rejections under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement, and the previously withdrawn rejection under 35 U.S.C. § 102 to the currently pending claims. Prior to addressing these rejections, Applicants would like to present the currently claimed invention in context.

#### **Applicants' Invention**

This invention is predicated on the discovery by the present inventors that stabilization of the alpha subunit of hypoxia inducible factor (HIF $\alpha$ ) in a subject leads to a decrease in blood

glucose levels in the subject. See specification as filed at, e.g., page 6, [0020] and [0022]. Therefore, a subject having diabetes, hyperglycemia, or elevated blood glucose levels can be effectively treated via stabilization of the alpha subunit of hypoxia inducible factor (HIF $\alpha$ ). See specification as filed at, e.g., page 14, [0059] and [0060], and page 18, [0072]. Prior to the present invention, the art provided no association between HIF and treatment of diabetes, between HIF and treatment of hyperglycemia, or between HIF and decreasing blood glucose levels. Applicants submit that the discovery of this association represents a pioneering discovery.

Based on the above, the claims now presented are directed to methods for “treating diabetes in a diabetic subject,” “treating hyperglycemia in a hyperglycemic subject,” and “decreasing blood glucose levels in a diabetic or hyperglycemic subject,” respectively. The treatment of diabetes or hyperglycemia or the decrease in blood glucose levels is achieved by administering to the subject an effective amount of “a HIF $\alpha$  stabilizer” or a “HIF hydroxylase inhibitor.”

Methods of stabilizing HIF $\alpha$  were well-known in the art at the time of the present invention, and are described in the specification as filed at, e.g., pages 4 and 5, [0014]; pages 15 and 16, [0063]; and page 16, [0064]. One method of stabilizing HIF $\alpha$  is to inhibit the activity of a HIF hydroxylase enzyme. Page 16, [0064]. The HIF hydroxylase enzyme can be a HIF prolyl hydroxylase. Pages 16 and 17, [0066]. The stabilization of HIF $\alpha$ , or the inhibition of HIF hydroxylase activity, can be achieved by administration of a HIF $\alpha$  stabilizer or a HIF hydroxylase inhibitor. Pages 4 and 5, [0014]; page 16, [0064] and [0067].

HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors were well-known and available to one of skill in the art at the time of filing of the present application. In fact, the art at the time of filing of the present application was replete with numerous stabilizers of HIF $\alpha$  or inhibitors of HIF hydroxylase, and exemplary such compounds, and their use in the novel claimed methods, are clearly described in the specification as filed. See page 35, [0131], to page 37, [0139]. In

particular, at pages 35-36, [0134], the specification states that “[s]mall molecule inhibitors of HIF hydroxylases have...been identified,” and cites by way of example “International Publication Nos. WO 02/074981, WO 03/049686, and WO 03/080566,” each of which publication is incorporated by reference into the present specification in its entirety. In further describing HIF stabilizers and HIF hydroxylase inhibitors for use in the present methods, the specification continues at page 36, [0135]: “...compounds of the invention include, but are not limited to, iron chelators, 2-oxoglutarate mimetics, and modified amino acid, e.g., proline or asparagine, analogs.” The specification as filed provides both functional and structural definitions of compounds and classes of compounds to be used in the claimed methods, stating at page 36, [0136], that compounds for use in the present invention include “structural mimetics of 2-oxoglutarate” which “may inhibit the target 2-oxoglutarate dioxygenase enzyme competitively with respect to 2-oxoglutarate and noncompetitively with respect to iron.” The specification as filed further states at page 36, [0136], that “[s]pecifically contemplated are compounds described, e.g., in Majamaa, *et al.*, *supra* [(1985) Biochem J 229:127-133]; Kivirikko and Myllyharju (1998) Matrix Biol 16:357-368; Bickel *et al.* (1998) Hepatology 28:404-411; Friedman *et al.* (2000) Proc Natl Acad Sci USA 97:4736-4741; Franklin (1991) Biochem Soc Trans 19:812-815; Franklin *et al.* (2001) Biochem J 353:333-338; and International Publication No. WO 03/049686, all incorporated by reference herein in their entirety.”

The specification as filed identifies heterocyclic carboxamides as a preferred compound class, and points to more structurally limited subgenera of this class as specifically preferred (“[s]pecifically preferred heterocyclic carboxamides include, e.g., isoquinolines, quinolines, pyridines, cinnolines, carbolines, etc.”). Page 37, [0138]. Further identification of structural features is provided as the specification defines, for example, heterocyclic carbonyl glycines as exemplary compounds for use in the present methods, and further defines this class by identifying substituted quinoline-2-carboxamides; substituted isoquinoline-3-carboxamides; 3-methoxy pyridine carbonyl glycines; 3-hydroxypyridine carbonyl glycines; and 5-sulfonamidocarbonyl pyridine carboxylates as exemplary compounds suitable for use in the present methods. Page 36, [0137]. Various representative species of these subgenera are

described at page 37, [0139], and the use of these representative compounds is described in the examples. See Examples 2-4, 6-10, 12, and 13.

An exemplary summary of HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors known and available to one of skill in the art at the time of filing of the present application can be found in the teachings of HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors provided in commonly owned International Publication No. WO 03/049686 (hereinafter the '686 Publication), which publication is incorporated by reference in its entirety in the present specification. The '686 Publication is directed to methods of stabilizing HIF $\alpha$  and inhibiting HIF hydroxylase and teaches several genera and subgenera of compounds that are useful for stabilizing HIF $\alpha$  and inhibiting HIF hydroxylase, which compounds were known in the art and available to one of skill at the time of filing of the present application. See, for example, the '686 Publication, at least at page 33, [0081], through page 49, [0093], identifying exemplary classes, formulae, and specific species of HIF $\alpha$  stabilizers or HIF hydroxylase inhibitors. For the convenience of the Office, a copy of the '686 Publication is enclosed herewith.

In addition to what is taught in the present specification and what was known in the art at the time of filing of the present application, Applicants note that the specification as filed teaches methods for identifying HIF $\alpha$  stabilizers. See specification at Example 14, page 55, [0199] to page 56, [0203].

In summary, the current claims are directed to methods for treating diabetes, treating hyperglycemia, or decreasing blood glucose levels by stabilizing HIF $\alpha$  or inhibiting HIF hydroxylase. The invention derives from the pioneering discovery made by the present inventors that treatment of diabetes or hyperglycemia, or a decrease in blood glucose levels, could be achieved via HIF $\alpha$  stabilization or HIF hydroxylase inhibition. The stabilization of HIF $\alpha$  or inhibition of HIF hydroxylase may be accomplished by administering an effective amount of any of a number of HIF $\alpha$  stabilizers or HIF hydroxylase inhibitors described in detail in the present specification or widely known and available in the art at the time of filing of the present

application. The present invention is thus not an identification of novel compounds, but relates rather to a new and heretofore unavailable use of HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors, classes of which compounds were known and available in the art at the time of filing of the present application.

**Claim Rejections under 35 U.S.C. § 102**

In the Office Actions dated February 22, 2007 (Part of Paper No./Mail Date 20070204), and June 13, 2007 (Part of Paper No./Mail Date 20070605), claims 1-37 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Müller (EP 0878480). While this rejection was previously overcome, for the convenience of the Office in considering the newly presented claims, Applicants readdress this rejection below.

To anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.* 802 F.2d 1367, 1379 (Fed. Cir. 1986). Applicants submit that Müller does not teach each element of the currently pending claims.

Specifically, Müller is directed to “a method for the improvement of neuronal regeneration, a medicament for the improvement of neuronal regeneration and use of an inhibitor substance.” See, Müller at page 2, column 1, lines 3-6. In particular, Müller teaches preventing or inhibiting basal membrane formation by applying an inhibitor substance of the synthesis and/or assembly of basal membrane building elements. See, Müller at page 1, column 1, lines 25-48.

The currently presented claims are directed to methods of treating diabetes, treating hyperglycemia, or decreasing blood glucose levels by administering an effective amount of a HIF $\alpha$  stabilizer or a HIF hydroxylase inhibitor to a diabetic or hyperglycemic subject. Müller does not teach treating diabetes, treating hyperglycemia, or decreasing blood glucose levels, and therefore fails to teach an element of the claimed invention. Additionally, Müller does not teach administering an effective amount of a HIF $\alpha$  stabilizer or a HIF hydroxylase inhibitor to a

diabetic or hyperglycemic subject, and therefore fails to teach each element of the claimed invention.

For at least the above reasons, Müller does not teach each element of the claimed invention, and thus fails to anticipate new claims 38-48. Accordingly, Applicants request that the previously made rejection under 35 U.S.C. § 102(b) remain withdrawn.

**Claim Rejections under 35 U.S.C. § 112, first paragraph**

In the Office Action dated June 13, 2007, claims 1-37 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly not complying with the written description requirement. In the Office Action dated March 20, 2008, claims 2, 5, 6, 8, 10, 12-31 and 34-36 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly not complying with the written description requirement. While the Office has not yet considered new claims 38-48, in an effort to expedite prosecution, Applicants will discuss the previous written description rejections in light of the currently pending claims.<sup>1</sup> Applicants respectfully submit that the currently pending claims fully comply with the written description requirement of 35 U.S.C. § 112.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention at the time of filing. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116.

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<sup>1</sup> In the Office Action dated March 20, 2008, on page 4-5 (Part of Paper No./Mail Date 20080310), the Office asserted that a recitation of a species falling within the scope of a genus may not provide adequate written description of the genus unless the species is representative, or definitive structural features are described. The Office concluded that the term “structural mimetic of 2-oxoglutarate” — which appeared in the claims as amended at that time, now canceled — was not described in the specification so as to “provide sufficient structural teachings to make and use the invention as envisioned.” Office Action, page 6. While Applicants disagree with this characterization, the pending claims do not recite this term, and, accordingly, Applicants do not address herein whether the term “structural mimetic of 2-oxoglutarate” is adequately described in the present specification. As pending new claims 38-48 more closely correspond to the claims as originally filed, Applicants do address herein the rejection under 35 U.S.C. § 112, written description, as stated in the Office Action dated June 13, 2007 (Part of Paper No./Mail Date 20070605).

As described above, the present invention derives from the discovery by the present inventors that stabilization of HIF $\alpha$  leads to a decrease in blood glucose levels, and that treatments for diabetes and hyperglycemia and a decrease in blood glucose levels can thus be accomplished via HIF $\alpha$  stabilization. HIF $\alpha$  can be stabilized by a variety of methods known in the art at the time of filing of the present application, including by inhibition of HIF hydroxylase. The present methods thus relate to a new and heretofore unavailable use of HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors, classes of which compounds were known and available in the art at the time of filing of the present application.

**I. One of Ordinary Skill in the Art Would Understand that Applicants Were in Possession of the Claimed Invention at the Time of Filing**

In making the previously stated rejection, the Office stated on page 4 of the Action dated June 13, 2007, that:

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises the stabilizing [of] the alpha subunit of hypoxia inducible factor  $\alpha$  . . . in a subject via administering to said subject a compound that inhibits hydroxylation of hypoxia inducible factor  $\alpha$  . . . .

Applicants submit that this analysis is not relevant to current claims 38-48. In particular, these statements do not address the substantial and detailed description of HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors provided in the specification and neglect to account for what one of skill in the art knew at the time of filing.

As discussed in the specification at page 35, [0131], to page 37, [0139], HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors were well known in the art at the time of the filing of the present invention, as was their use for stabilizing the alpha subunit of hypoxia inducible factor. Information which is well-known in the art need not be described in detail in the specification. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986). One of skill in the art, as explained above, would have been well aware at



the time of filing of the present invention of a number of structurally diverse HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors.

Representative of the information that would have been well-known to and available to one of skill in the art at the time of filing is the exemplary disclosure found in commonly owned International Publication No. WO 03/049686 (the '686 Publication), discussed *supra*, and incorporated by reference in its entirety into the present application. As previously described, the '686 Publication is directed to methods of stabilizing HIF $\alpha$  and inhibiting HIF hydroxylase and teaches several genera and subgenera of compounds that are useful for stabilizing HIF $\alpha$  and inhibiting HIF hydroxylase, which compounds were known in the art and available to one of skill at the time of filing of the present application. See, for example, the '686 Publication, at least at page 33, [0081], through page 49, [0093], identifying exemplary classes, formulae, and specific species of HIF $\alpha$  stabilizers or HIF hydroxylase inhibitors. As noted previously, a copy of the '686 Publication is enclosed herewith for the Office's convenience.

Moreover, the specification provides significant additional description of HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors beyond a simple reference to prior art. In particular, at pages 35-36, [0134], the specification states that "[s]mall molecule inhibitors of HIF hydroxylases have...been identified," and cites by way of example "International Publication Nos. WO 02/074981, WO 03/049686, and WO 03/080566," each of which publication is incorporated by reference into the present specification in its entirety. In further describing HIF stabilizers and HIF hydroxylase inhibitors for use in the present methods, the specification continues at page 36, [0135]: "...compounds of the invention include, but are not limited to, iron chelators, 2-oxoglutarate mimetics, and modified amino acid, e.g., proline or asparagine, analogs." The specification as filed provides both functional and structural definitions of compounds and classes of compounds to be used in the claimed methods, stating at page 36, [0136], that compounds for use in the present invention include "structural mimetics of 2-oxoglutarate" which "may inhibit the target 2-oxoglutarate dioxygenase enzyme competitively with respect to 2-oxoglutarate and noncompetitively with respect to iron." The specification as filed further

states at page 36, [0136] that “[s]pecifically contemplated are compounds described, e.g., in Majamaa, *et al.*, *supra* [(1985) Biochem J 229:127-133]; Kivirikko and Myllyharju (1998) Matrix Biol 16:357-368; Bickel *et al.* (1998) Hepatology 28:404-411; Friedman *et al.* (2000) Proc Natl Acad Sci USA 97:4736-4741; Franklin (1991) Biochem Soc Trans 19:812-815; Franklin *et al.* (2001) Biochem J 353:333-338; and International Publication No. WO 03/049686, all incorporated by reference herein in their entirety.”

Additionally, the specification as filed identifies heterocyclic carboxamides as a preferred compound class, and points to more structurally limited subgenera of this class as specifically preferred (“[s]pecifically preferred heterocyclic carboxamides include, e.g., isoquinolines, quinolines, pyridines, cinnolines, carbolines, etc.”) Page 37, [0138]. Further identification of structural features is provided as the specification defines, for example, heterocyclic carbonyl glycines as exemplary compounds for use in the present methods, and further defines this class by identifying substituted quinoline-2-carboxamides; substituted isoquinoline-3-carboxamides; 3-methoxy pyridine carbonyl glycines; 3-hydroxypyridine carbonyl glycines; and 5-sulfonamidocarbonyl pyridine carboxylates as exemplary compounds suitable for use in the present methods. Page 36, [0137]. Various representative species of these subgenera are described at page 37, [0139], and the use of these representative compounds is described in the examples. See Examples 2-4, 6-10, 12, and 13. Accordingly, one of skill in the art would clearly recognize from the extensive description provided in the present application that Applicants were in possession of representative genera, subgenera, and exemplary species of HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors for use in the claimed methods.

Applicants submit that the Office previously failed to recognize the scope of Applicants’ claimed invention and erroneously applied a written description rejection to the claimed invention, and that pending claims 38-48, as evidenced by the discussion above, are free of any rejection under 35 U.S.C. 112, first paragraph, written description.

**II. *Regents of the University of California v. Eli Lilly & Co.* Is Not Relevant and Does Not Apply to the Currently Pending Claims**

As stated above, the currently claimed invention is directed to methods of treating diabetes, treating hyperglycemia, or decreasing blood glucose levels in diabetic or hyperglycemic subjects by administering an effective amount of a HIF $\alpha$  stabilizer or HIF hydroxylase inhibitor. The specification teaches numerous compounds that can act as HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors and these and many other HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors are known in the art, and were known in the art at the time of filing of the present application. Further, Applicants have reduced the invention to practice by testing a number of representative species of known HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors in various assays, both *in vitro* and *in vivo*, which assays are readily correlated to treatment of diabetes, treatment of hyperglycemia, or decreasing blood glucose levels. See, e.g., Examples 6, 7, and 8 of the specification as filed.

The Office has previously alleged lack of written description, apparently on the basis of the absence of a structural limitation of the HIF $\alpha$  stabilizer or HIF hydroxylase inhibitor in the claims. Applicants maintain that HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors were known in the art. Recitation of a *known* structure is not required to provide an adequate written. See, *Faulkner v. Inglis*, 448 F.3d 1357 (Fed. Cir. 2006). “[T]here is no *per se* rule that an adequate description of an invention that involves a biological macromolecule must contain a recitation of known structure.” *Faulkner* at 1366. Moreover, the present invention is not directed to novel compounds that stabilize HIF $\alpha$  or inhibit HIF hydroxylase or to novel methods of stabilizing HIF $\alpha$  or inhibiting HIF hydroxylase. Rather, the invention is directed to novel methods of treating diabetes, treating hyperglycemia, or decreasing blood glucose levels by stabilizing HIF $\alpha$  or inhibiting HIF hydroxylase.

In making the written description rejections as stated in the Office Actions dated June 13, 2007, and March 20, 2008, the Office relied on *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1569 (Fed. Cir. 1997). See Office Action dated June 13, 2007, at

page 3; see Office Action dated March 20, 2008, at page 3. This reliance, however, is misplaced. The present case is easily distinguished from that of *Lilly*.

In *Lilly*, U.S. Patents 4,652,525 (the ‘525 Patent) and 4,431,740 (the ‘740 patent) were at issue. Claim 5 of the ‘525 patent was directed to a microorganism containing a human insulin cDNA. The claimed invention was predicated on a novel cDNA, but the specification in that case did not describe the cDNA structurally and instead provided only a constructive example of how to obtain the cDNA. The court held that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Lilly*, 119 F.3d at 1568. In contrast, the terms “HIF $\alpha$  stabilizer” and “HIF hydroxylase inhibitor” as recited in the currently pending claims are not mere names. As detailed above, the specification is replete with description of what these materials consist of. Further, this description is provided in the presence of extensive knowledge in the art as to what the materials consist of. The written description requirement must be applied in the context of the particular invention and the state of the knowledge. *Capon v. Eshhar*, 418 F.3d 1349, 1358 (Fed. Cir. 2005). “The descriptive text needed to meet [this] requirement[] varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence.” *Capon*, 418 F.3d at 1357. Therefore, in evaluating the written description provided for the presently claimed invention, the state of the prior art knowledge of HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors, as well as the extensive description in the specification, must be considered. When this is done, it is clear that the presently claimed invention is supported by adequate written description.

Further citing to *Lilly*, the Office Action dated June 13, 2007, stated at page 3 that:

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

*Lilly* at 1569. In *Lilly*, the genus at issue (cDNA encoding vertebrate insulin) was supported by the description of the structure of a single member (cDNA encoding rat insulin). No other species within the genus were described or known in the art. This is not the case for the present invention for which description of a multitude of species is provided. Furthermore, the court, since *Lilly*, has recognized that "...the determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter." *Capon*, 418 F.3d at 1359. Applicants respectfully direct the Office to the discussions, *supra*, describing the state of the art and Applicants' teachings of HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors as detailed above. The abundance of the teachings and description identifying HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors provided in the specification, coupled with what was known in the art, clearly constitute an adequate representation of the genus of HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors used in the presently claimed methods.

Further, at page 4, the Office Action dated June 13, 2007, cites to the following footnote in *Lilly*:

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed.Cir.1993).

Applicants have described in the specification, by both incorporation by reference and by specific disclosures of HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors that are tested in the examples, HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors useful for practicing the invention. Suitable HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors are defined in the specification by structure, by chemical name, and by physical properties. Accordingly, Applicants have, in fact, conveyed the identity of HIF $\alpha$  stabilizers and HIF hydroxylase inhibitors that can be used in the

presently claimed methods. For at least the reasons set forth above, Applicants maintain that the invention as presently claimed is described in sufficient detail that one skilled in the art can reasonably conclude that the inventors had possession of the invention at the time of filing. Accordingly, Applicants submit that the rejection under 35 U.S.C. § 112 applied to now canceled claims 1-37 was not correctly applied to these claims, and cannot be correctly applied to new claims 38-48, and request that this rejection be withdrawn.

### **Conclusion**

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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